

Contains No CBI



TOXICOLOGY DEPARTMENT

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22 May - 2 MHD: 25

October 27, 1992

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US Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID No.: 8ECAP - 0004

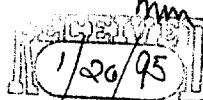
Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN 5266, Princeton, NJ 08543-5266) and its subsidiary Rhône-Poulenc Ag Company (RPAC), the attached study report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for a TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA.

The enclosed study report provides information on M&B 46030. Its CAS number and chemical index name are 120068-37-3 and 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile. This chemical is manufactured in Europe and imported by RPAC for pesticide research and development.

No claims of confidentiality are made for this submission. Please note that RPAC released previous confidentiality claims for the subject chemical on September 8, 1992. The title of the enclosed report is "M&B 46030: Combined Oncogenicity and Toxicity Study by Dietary Administration to CD Rats for 104 Weeks Followed by an 8 Week Reversibility Period on Completion of 52 Weeks of Treatment. Interim Synoptic Report: Week 0-Termination". The following is a summary of the adverse effects observed in this study.

This study is being submitted under Section 8(e) because of the clinical signs observed. Groups of CD rats (80/sex/group) were administered the test material at dietary levels of 0, 0.5, 1.5, 30, or 400 ppm in the diet. At 400 ppm eight males and six females died or were sacrificed in extremis during the first week of treatment. Convulsions lasting for between 5 and 25 minutes were noted shortly before death. Salivation, ataxia, and overactivity were also noted for a few of these animals. Convulsive episodes lasting between 20 seconds and 13 minutes were also noted in four males and three females during week 1 of the study. These animals appeared to recover afterwards. Due to the evidence of overt toxicity, the highest dietary level was lowered to 300



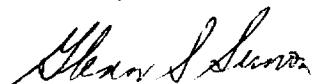
ppm at Week 2 of the study. However, an error was made in preparing the diets which was discovered at approximately Week 8, and the study was terminated.

Seven previous TSCA Section 8(e) notices were submitted on this chemical. The EPA Document Control Numbers for these submissions are 8EHQ-0191-1162S, 8EHQ-0391-1199S, 8EHQ-0591-1232S, 8EHQ-0791-1284S, 8EHQ-0791-1285S and 8EHQ-0891-1315S, and 8EHQ-0392-2540S. Also several Section 8(e) notices will be submitted on this compound under the CAP.

In total, RPI is submitting three copies of the enclosed report and this cover letter: an original and two copies.

Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

Sincerely,



Glenn S. Simon, PhD, DABT
Director of Toxicology

M&B 46030: COMBINED ONCOGENICITY
AND TOXICITY STUDY BY DIETARY
ADMINISTRATION TO CD RATS FOR
104 WEEKS FOLLOWED BY AN
8 WEEK REVERSIBILITY PERIOD
ON COMPLETION OF 52 WEEKS
OF TREATMENT

INTERIM SYNOPTIC REPORT :
WEEK 0-TERMINATION

Study Director

P. Aughton

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Date: 7 June 1991



LIFE SCIENCE RESEARCH

M&B 46030: COMBINED ONCOGENICITY
AND TOXICITY STUDY BY DIETARY
ADMINISTRATION TO CD RATS FOR
104 WEEKS FOLLOWED BY AN
8 WEEK REVERSIBILITY PERIOD
ON COMPLETION OF 52 WEEKS
OF TREATMENT

INTERIM SYNOPTIC REPORT : WEEK 0-TERMINATION

LSR Schedule No : RHA/312/46030
LSR Report No : 91/RHA312/0197

This report summarises the results obtained during the eight-week treatment period. The data has not been subjected to Quality Assurance Review.

Dietary concentrations of 0.5, 1.5, 30 and 400 ppm were selected by the Sponsor. There were, however, a high number of deaths during the first week of treatment among animals receiving 400 ppm, and this concentration was reduced to 300 ppm, from Week 2 onwards, at the request of the Sponsor. The instructions to Pharmacy for formulated diet were, however, erroneously amended and this resulted in animals of Groups 2, 3 and 4 receiving dietary concentrations of M&B 46030 which were 25% lower than intended during Weeks 2 to 4. The study was therefore terminated, without necropsy examination, after eight weeks of treatment at the request of the Sponsor. All data relating to this study are held in the archives of Life Science Research.

P. Aughton, B.Sc., Dip.R.C.Path.,
C.Biol., M.I.Biol.
(Study Director)

P.Aug
.....
Date: 7 June 91 ..

L. Freeman, B.Sc.
(Staff Toxicologist)

Linda Freeman
Date: 7 June 1991....

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1. SUMMARY

- 1.1 Groups of eighty male and eighty female CD rats received M&B 46030 continuously, via the diet, at concentrations of 0.5, 1.5, 30 and 400 ppm for eight weeks.

Following a number of deaths at 400 ppm in the first week of treatment the highest concentration was reduced to 300 ppm from Week 2 of treatment at the request of the Sponsor. A similarly constituted group received untreated diet and served to generate contemporaneous control data.

A summary of the findings is presented below.

- 1.2 The following changes in comparison with controls were noted:

400/300 ppm

Five males and five females were found dead and three males and one female were killed *in extremis* in the first week of treatment. Convulsions lasting for between five and 25 minutes were noted shortly before death for all those animals that were killed and for two of the males and one female that were found dead. Salivation, ataxia and overactivity were also noted for a few of these animals.

Convulsive episodes lasting for between 20 seconds and 13 minutes were also noted for four males and three females during Week 1 of treatment. These animals appeared to recover afterwards.

Markedly lower food consumption and bodyweight gain was noted for males and females during the first week of treatment. Thereafter food consumption was similar or slightly higher than control values and bodyweight gain was significantly higher than that of their respective controls. The overall weight gain was, however, significantly lower than that of control values.

The overall efficiency of food conversion was lower than that of the controls.

30, 1.5 and 0.5 ppm

There were no deaths.

Appearance and behaviour were unaffected by treatment.

Overall food consumption, bodyweight gain and efficiency of food conversion were similar to those of the controls.

FIGURE 1A
Group mean bodyweight versus period of treatment - males

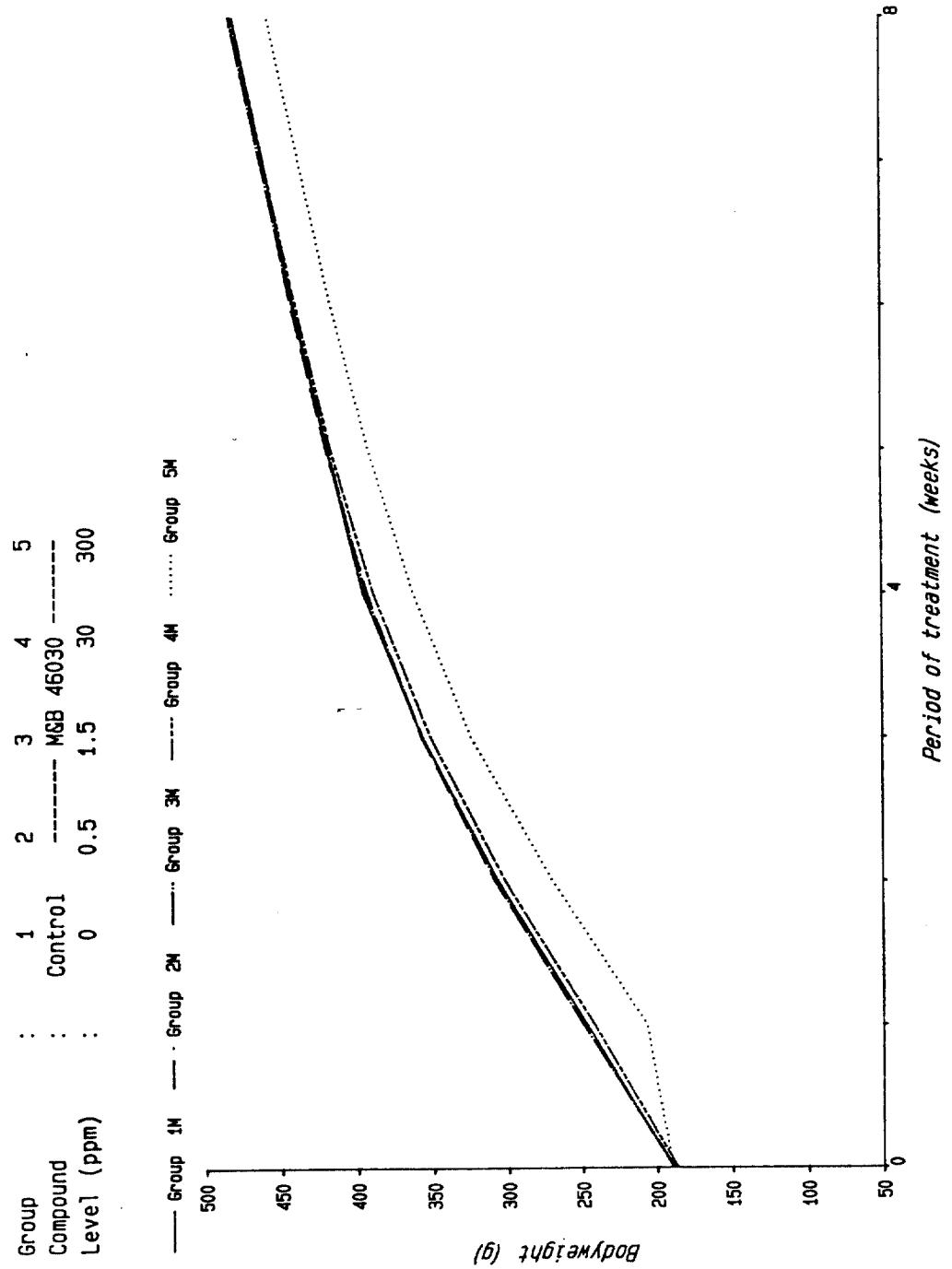
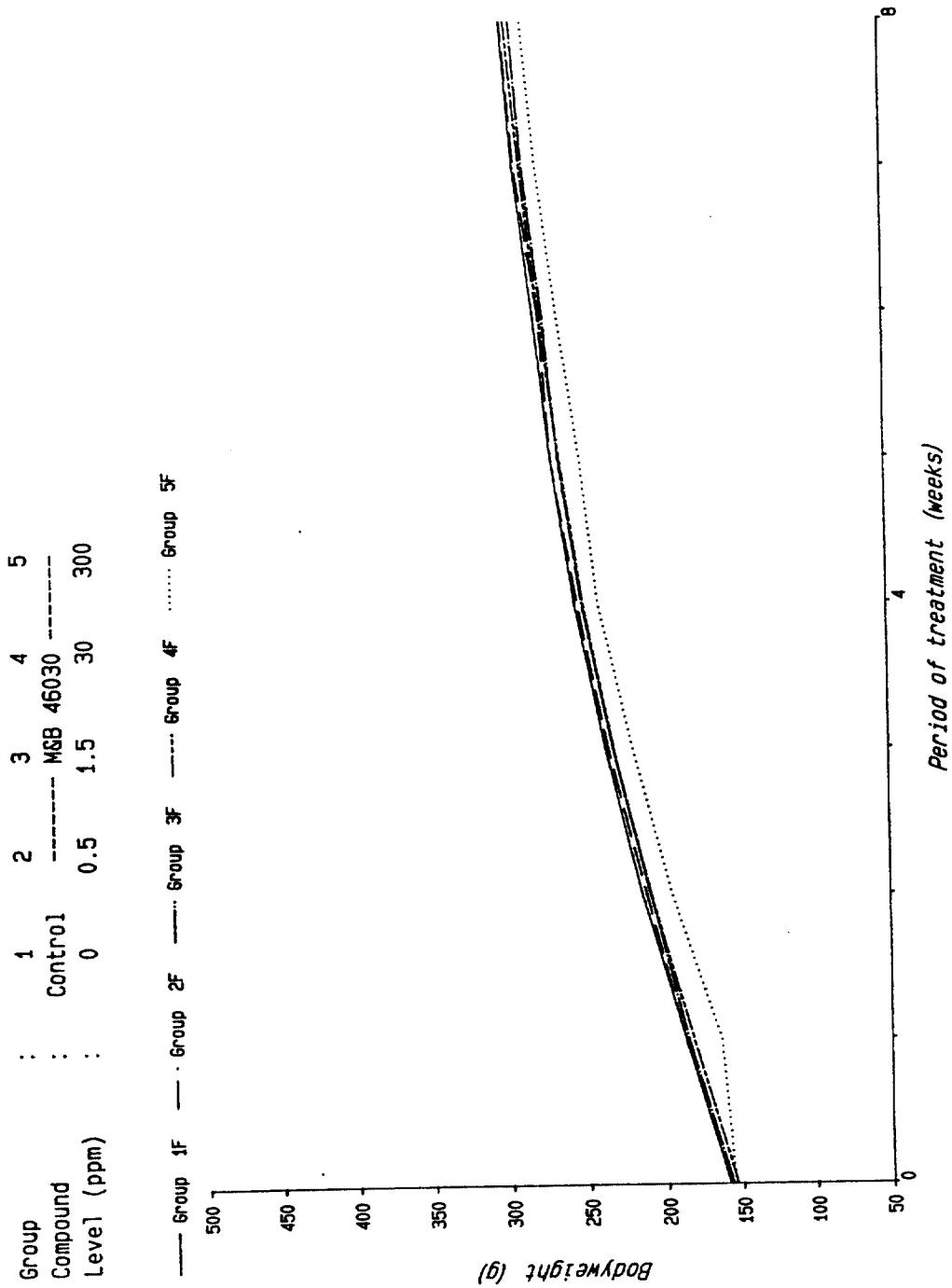


FIGURE 1B
Group mean bodyweight versus period of treatment - females



Signs - group distribution of observations								
Group	:	1	2	3	4	5		
Compound	:	Control	0.5	M6B 46030	1.5	30	300	*DRAFT*
Level (ppm)								
WEEKS 1 TO 8								
CATEGORY								
KEYWORD								
QUALIFIER								
*** TOP OF LIST ***								
SKIN ABRASION								
DRY								
BUILD (DEFORMITY)								
ABSENT APPENDAGE								
KINKED TAIL								
PARTIALLY ABSENT APPENDAGE								
BEHAVIOUR								
AGGRESSIVE								
EXCESSIVE CHEWING								
IRRITABLE								
OVERTACTIVE								
UNDERACTIVE								
VOCALIZATION								
SALIVATION								
COAT								
HAIRLOSS								
SKIN COLOUR								
BROWN								
REDDENING								
DISCHARGE								
AQUEOUS								
BLOOD								
EYES								
DRY								
PROMINENT								

TABLE 1 - continued.

Signs - group distribution of observations

Group Compound Level (ppm)	:	1 Control 0	2 0.5	3 1.5	4 30	5 300	*DRAFT*	Schedule number: RHA 312				
WEEKS 1 TO 8		NUMBER OF ANIMALS AFFECTED										
CATEGORY KEYWORD QUALIFIER		SEX: GROUP:	1 1	2 80	3 80	4 80	5 80	1 80	2 80	3 80	4 80	5 80
muscle reaction												
ATAXIA			0	0	0	0	2	0	0	0	0	0
CONVULSION			0	0	0	0	8	0	0	0	0	5
respiration												
FAST			0	0	0	0	0	0	0	0	0	0
IRREGULAR			0	0	0	0	1	0	0	0	0	0
skin encrustations												
SCAB			9	10	9	10	5	2	2	4	1	4
ULCERATION			0	1	1	0	0	0	0	0	0	1
staining												
BLACK			1	0	0	0	0	0	0	0	0	0
BROWN			1	1	1	1	3	4	5	2	8	2
YELLOW			0	0	0	0	0	1	0	0	1	
teeth												
ABSENT			0	0	1	0	0	0	0	0	0	0

*** END OF LIST ***

TABLE 2
Food consumption - group mean values (g/animal)

Group Compound Level (ppm)	1	Control					MAB 46030					300 *DRAFT*				
		0	0.5	1.5	30	300	4	5	6	7	8	9	10	11	12	13
SEX: GROUP:	MALE					FEMALE					FEMALE					
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
WEEK																
1	N MEAN	80	80	80	80	80	80	80	80	80	80	80	80	80	80	
	S.D.	181	187	9.8	7.4	9.4	179	127	146	149	141	140	140	140	103	
2	N MEAN	80	80	80	80	80	72	80	80	80	80	80	80	80	80	
	S.D.	190	196	8.0	6.5	6.6	192	185	150	146	144	148	148	148	149	
3	N MEAN	80	80	80	80	80	72	80	80	80	80	80	80	80	74	
	S.D.	200	202	7.6	7.8	8.7	201	154	155	155	155	156	156	156	157	
4	N MEAN	79	80	80	80	80	72	80	80	80	80	80	80	80	74	
	S.D.	199	199	9.9	10.1	10.1	198	200	201	154	157	154	156	156	162	
5	N MEAN	79	80	80	80	80	72	80	80	80	80	80	80	80	74	
	S.D.	192	196	7.6	12.8	9.5	193	201	154	157	154	156	156	156	19.1	
6	N MEAN	79	80	80	80	80	72	80	80	80	80	80	80	80	74	
	S.D.	192	193	11.3	8.2	7.9	192	195	153	156	152	152	152	152	160	
7	N MEAN	79	80	80	80	80	72	80	80	80	80	80	80	80	74	
	S.D.	198	197	11.5	9.3	9.3	195	196	202	150	152	149	152	152	150	
8	N MEAN	79	80	80	80	80	72	80	80	80	80	80	80	80	74	
	S.D.	196	198	11.2	8.9	12.7	196	199	152	153	153	151	153	153	154	
Total 1-8		1548	1568	1551	1549	1511	1213	1221	1197	1213	1195					
As % of control		101	100	100	98	101	99	100	99	100	99					

TABLE 3A
 Bodyweight - group mean values (g)
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WEEK	SEX:	GROUP:	MALE					FEMALE					5
			1	2	3	4	5	1	2	3	4	5	
0	N	80	80	80	80	80	80	80	80	80	80	80	80
	MEAN	190	189	189	187	190	159	157	157	157	154	154	155
	S.D.	12.1	12.7	12.0	11.5	12.7	11.3	11.5	10.7	10.7	9.7	9.7	11.5
1	N	80	80	80	80	80	72	80	80	80	80	80	74
	MEAN	247	249	249	242	207	187	188	186	186	182	182	164
	S.D.	19.2	16.4	16.1	14.7	14.9	18.1	13.4	14.0	14.0	13.0	13.0	10.5
2	N	80	80	80	80	80	72	80	80	80	80	80	74
	MEAN	306	309	308	302	269	215	212	209	209	210	210	195
	S.D.	22.1	21.4	20.7	19.4	19.8	18.4	15.9	17.0	17.0	17.7	17.7	13.5
3	N	79	80	80	80	80	72	80	80	80	80	80	74
	MEAN	357	357	357	351	324	237	235	232	232	232	232	220
	S.D.	25.4	24.7	24.8	25.4	24.8	22.7	18.6	18.1	18.1	20.9	20.9	15.5
4	N	79	80	80	80	80	72	80	80	80	80	80	74
	MEAN	396	393	393	389	362	256	254	251	251	250	250	241
	S.D.	31.3	31.2	30.9	31.4	31.4	25.5	20.6	21.6	21.6	23.2	23.2	18.2
5	N	79	80	80	80	80	72	80	80	80	80	80	74
	MEAN	419	420	419	417	392	270	270	265	265	264	264	251
	S.D.	37.1	35.1	32.6	33.7	34.3	27.6	23.9	23.0	23.0	24.5	24.5	21.8
6	N	79	80	80	80	80	72	80	80	80	80	80	74
	MEAN	441	443	442	439	416	280	277	274	274	277	277	265
	S.D.	41.5	39.7	36.9	38.3	38.0	31.7	32.7	25.3	25.3	26.6	26.6	23.3
7	N	79	80	80	80	80	72	80	80	80	80	80	74
	MEAN	460	461	462	460	437	292	291	286	286	287	287	277
	S.D.	43.6	43.0	40.7	41.9	41.4	30.4	26.3	27.0	27.0	27.8	27.8	26.2
8	N	79	80	80	80	80	72	80	80	80	80	80	74
	MEAN	480	481	483	482	457	300	299	293	293	296	296	286
	S.D.	47.7	44.6	43.7	46.0	43.1	32.7	29.3	29.1	29.1	29.1	29.1	28.2

TABLE 3B
Bodyweight gain - group mean values (g)

Group		1	2	3	4	5	
Compound	Control	0.5	1.5	30	300		*DRAFT*
Level (ppm)							
SEX:	MALE						
GROUP:	1	2	3	4	5		
WEEK							
0-1	N	80	80	80	72	80	80
	MEAN	57	60	55	17 ^b	28	28
	S.D.	12.0	5.7	7.7	7.3	12.7	7.5
							10.3
1-8	N	79	80	80	72	80	80
	MEAN	233	232	233	251 ^a	112	114
	S.D.	41.2	34.2	33.4	37.8	36.3	19.5
							122 ^a
							22.1
0-8	N	79	80	80	72	80	80
	MEAN	290	292	294	268 ^b	141	136
	S.D.	42.0	37.6	37.6	41.3	36.9	23.3
							130 ^a
							25.3

a Significantly different from controls, P < 0.05
 b Significantly different from controls, P < 0.01

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TABLE 4

Food conversion efficiency - group mean values (%)

Group Compound Level (ppm)	SEX: GROUP:	MALE					FEMALE					*DRAFT*
		1	2	3	4	5	1	2	3	4	5	
WEEK												
1 N MEAN 31.5	16	16	31.9	33.2	30.9	11.4	16	16	16	16	16	6.1
S.D. 3.0			1.5	2.1	2.1	3.5	3.6	2.4	2.6	2.5	3.6	
2 N MEAN 31.2	16	16	30.4	30.2	16	16	16	16	16	16	16	21.1
S.D. 3.6			2.2	1.4	1.5	1.7	3.8	1.7	1.6	2.6	2.3	
3 N MEAN 24.8	16	16	24.0	24.3	16	16	16	16	16	16	16	15.7
S.D. 2.4			1.5	1.9	1.7	1.7	1.8	1.6	3.5	2.6	1.9	
4 N MEAN 19.5	16	16	17.7	18.6	16	16	16	16	16	16	16	13.0
S.D. 2.3			4.1	1.9	1.0	1.8	2.3	2.5	1.7	1.9	1.7	
5 N MEAN 12.1	16	16	13.9	13.0	16	16	16	16	16	16	16	6.6
S.D. 3.5			3.5	2.3	14.4	14.8	9.2	10.3	9.2	9.1	9.1	
6 N MEAN 11.5	16	16	11.7	12.0	11.8	12.5	6.6	4.3	4.7	2.0	3.3	2.4
S.D. 1.7			2.0	1.9	2.2	1.9	4.1	4.7	2.1	2.0	2.2	
7 N MEAN 9.5	16	16	9.5	10.5	10.6	10.4	7.7	9.4	7.6	16	16	7.8
S.D. 2.1				1.5	4.1	2.1	4.0	4.6	2.1	1.4	1.4	3.7
8 N MEAN 10.0	16	16	10.1	10.4	16	16	16	16	16	16	16	5.6
S.D. 2.0			3.7	1.6	3.1	1.6	1.6	1.7	2.6	1.6	1.6	
1-8	18.8	18.6	19.0	19.1	17.4	11.6	11.7	11.7	11.4	11.8	10.6	

TABLE 5
Achieved dosages - group mean values

Group	:	1	2	3	4	5		
Compound	:	Control	-	M&B	46030	-		Schedule Number : RHA 312
Level (ppm)	:	0	0.5	1.5	30	300		
							MALE	
SEX:							1	
GROUP:		1	2	3	4	5	2	
WEEK							3	
							4	
							5	
1		0.0	0.061	0.179	3.59	37.2	0.0	0.062
2		0.0	0.038*	0.112*	2.27*	33.3	0.0	0.039*
3		0.0	0.032*	0.097*	1.98*	29.0	0.0	0.038*
4		0.0	0.029*	0.085*	1.74*	25.1	0.0	0.035*
5		0.0	0.034	0.102	2.06	22.9	0.0	0.042
6		0.0	0.032	0.096	1.93	20.7	0.0	0.041
7		0.0	0.031	0.092	1.87	20.3	0.0	0.038
8		0.0	0.030	0.089	1.79	19.1	0.0	0.037
1-8		0.0	0.036	0.107	2.15	26.0	0.0	0.042

* Calculated using erroneously low dietary concentrations

TABLE 6
Macropathology - group distribution of findings for animals killed or dying during the treatment period.

Group		1	2	3	4	5	NUMBER OF ANIMALS - AFFECTED						
Compound	: Control	-	M&B 46030	-	30	300	*INTERIM*						
Level (ppm)	: 0	0.5	1.5										
Table includes: SEX=ALL; GROUP=ALL; WEEKS=1-8 DEATH=UNSCHED; SUBSET=ALL													
ORGAN AND KEYWORD(S) OR PHRASE							SEX: MALE	SEX: FEMALE					
AORTA	** TOP OF LIST **	NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0
ADRENALS (L&R)	DARK	NUMBER EXAMINED:	0	0	0	0	1	0	0	0	0	0	0
BRAIN X 3		NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0
BRONCHI		NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0
Caecum	ABNORMAL CONTENTS	NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0
Colon	ABNORMAL CONTENTS	NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0
Duodenum	ABNORMAL CONTENTS	NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0
Epididymides L&R		NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0
Femur Inc.Jt X2		NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0
Heart, Auricle		NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0
Heart, Ventricle		NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0
Ileum	ABNORMAL CONTENTS	NUMBER EXAMINED:	0	0	0	0	1	0	0	0	0	0	0
Jejunum	ABNORMAL CONTENTS	NUMBER EXAMINED:	1	0	0	0	8	0	0	0	0	0	0

TABLE 6 - continued.
Macropathology - group distribution of findings for animals killed or dying during the treatment period.

		NUMBER OF ANIMALS - AFFECTED				
		FEMALE				
		MALE				
Group	Compound	1	2	3	4	5
Level (ppm)		Control	0.5	M&B 46030	1.5	30
300 *INTERIM*						
Table includes:						
SEX=ALL; GROUP=ALL; WEEKS=1-8						
DEATH=UNSCHED; SUBSET=ALL						
ORGAN AND KEYWORD(S) OR PHRASE						
KIDNEYS (L&R)		1	0	0	0	0
L N MANDIBULAR		0	0	0	0	0
DARK		0	0	0	0	0
L N MESENTERIC		1	0	0	0	0
APPEAR LARGE		0	0	0	0	0
DARK		0	0	0	0	0
LIVER X 2		1	0	0	0	0
SWOLLEN		0	0	0	0	0
PALE		0	0	0	0	0
LT EYE		1	0	0	0	0
LUNGS X 2		1	0	0	0	0
INCOMPLETE COLLAPSE		0	0	0	0	0
AREA(S) OF CHANGE		0	0	0	0	0
MAMMARY A.CAUD		1	0	0	0	0
OESOPHAGUS		1	0	0	0	0
LEFT OPTIC NERVE		1	0	0	0	0
OVARIES (L&R)		0	0	0	0	0
PANCREAS		1	0	0	0	0
PARATHYROIDS L&R		1	0	0	0	0
PITUITARY		1	0	0	0	0

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TABLE 6 - continued.

Macropathology - group distribution of findings for animals killed or dying during the treatment period.

		NUMBER OF ANIMALS - AFFECTED				
		SEX: MALE FEMALE				
		GROUP: -1- -2- -3- -4- -5- -6- -7-				
		NUMBER:	1	0	0	0
ORGAN AND KEYWORD(S) OR PHRASE						
PROSTATE		NUMBER EXAMINED:	1	0	0	0
SEX=ALL; GROUP=ALL; WEEKS=1-8 DEATH=UNSCHED; SUBSET=ALL		NUMBER EXAMINED:	0	0	0	0
RECTUM		NUMBER EXAMINED:	1	0	0	0
ABNORMAL CONTENTS		NUMBER EXAMINED:	0	0	0	0
SCIATIC N.LT		NUMBER EXAMINED:	1	0	0	0
SEMINAL VESICLES		NUMBER EXAMINED:	1	0	0	0
SK. MUSCLE THIGH		NUMBER EXAMINED:	1	0	0	0
SKIN		NUMBER EXAMINED:	1	0	0	0
PERINEAL STAINING HAIRLESS MODERATE		0	0	0	0	0
FACIAL STAINING		0	0	0	0	0
SPINAL C. CERV		NUMBER EXAMINED:	1	0	0	0
SPINAL C. LUMB		NUMBER EXAMINED:	1	0	0	0
SPINAL C. THOR		NUMBER EXAMINED:	1	0	0	0
SPLEEN		NUMBER EXAMINED:	1	0	0	0
STERNUM/HAR X 2		NUMBER EXAMINED:	1	0	0	0
STOMACH X 2		NUMBER EXAMINED:	1	0	0	0
ABNORMAL CONTENTS		0	0	0	0	0
LEFT SUBMANDIB SL.GL		NUMBER EXAMINED:	1	0	0	0
TESTES (L&R)		NUMBER EXAMINED:	1	0	0	0

TABLE 6 - continued.

Macropathology - group distribution of findings for animals killed or dying during the treatment period.

Group	:	1	2	3	4	5	NUMBER OF ANIMALS - AFFECTED		
Compound	:	Control		M&B 46030			SEX:	MALE	FEMALE
Level (ppm)	:	0	0.5	1.5	30	300	GROUP:	-1-	-2-
INTERIM									
Table includes:									
SEX=ALL; GROUP=ALL; WEEKS=1-8									
DEATH=UNSCHED; SUBSET=ALL									
ORGAN AND KEYWORD(S) OR PHRASE									
THYMUS AREA(S) OF CHANGE									
THYROIDS (L&R)	NUMBER EXAMINED:	1	0
TRACHEA	NUMBER EXAMINED:	0	0
URINARY BLADDER	NUMBER EXAMINED:	1	0
UTERINE CERVIX	NUMBER EXAMINED:	1	0
UTERUS	NUMBER EXAMINED:	0	0
VAGINA	NUMBER EXAMINED:	0	0
L N THYMIC	NUMBER EXAMINED:	1	0
DARK	NUMBER EXAMINED:	0	0
MISCELLANEOUS	NUMBER EXAMINED:	1	0
TONGUE	NUMBER EXAMINED:	0	0
TRAUMA	** END OF LIST **		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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Rhône-Poulenc
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Research Triangle Park, North Carolina 27709

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 30 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12197A



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Triage of 8(e) Submissions

Date sent to triage: MAY 10 1995

NON-CAP

CAP

Submission number: 12197A

TSCA Inventory:

Y N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX *NEUR* CTOX EPI RTOX GTOX
STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

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entire document

0 1 2

pages

12

pages

12, TAB

Notes:

Contractor reviewer:

DR

Date:

2/22/95

CECAT STRIAGE TRACKING DBASE ENTRY FORM

OBCATS DATA:

Submission # 8EHQ-1192 - 12197 SEQ. A

TYPE INT SUPP FLWP

SUBMITTER NAME: phone - Poujanc Inc

SUB. DATE: 10/27/92 ONS DATE: 11/02/92 CRAD DATE: 01/26/95

DISPOSITION:

(639) REFER TO CHEMICAL SCREENING

(698) CAP NOTICE

INFORMATION REQUESTED: FLWP DATE:

0501 NO INFO REQUESTED

0502 INFO REQUESTED (TECH)

0503 INFO REQUESTED (VOL ACTIONS)

0504 INFO REQUESTED (REPORTING RATIONALE)

0406 APP USE DISCONTINUED

0407 PRODUCTION DISCONTINUED

0408 CONFIDENTIAL

VOLUNTARY ACTIONS:

(040) NO ACTION REQUESTED

0402 STUDIES PLANNED/DAY/NIGHT

0403 NOTIFICATION OF WORKERS/1000hrs

0404 LABEL/MSDS (CHANCES)

0405 PROCESS/HANDLING (CHANCES)

0407 PRODUCTION DISCONTINUED

0408 CONFIDENTIAL

1H - Pyrazole - 3 - carbendazole, 5 - amino - 1 - [2,6 - dihalo - 4 - (trifluoromethyl)phenyl] - 4 - [(trifluoromethyl)sulfonyl] -INFORMATION TYPE: P.F.C.INFORMATION TYPE: CASE#INFORMATION TYPE: P.F.C.INFORMATION TYPE: P.F.C.

0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCCRREL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER. INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0248 PRODUSE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PRODCOMP/CHM ID	01 02 04	0249 MSDS	01 02 04
0210 ACUTE TOX (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0251 OTHER	01 02 04
0211 CHR. TOX (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
0215		0240 METAB/PHARMACO (HUMAN)	01 02 04		

INFORMATION TYPE: P.F.C.INFORMATION TYPE: P.F.C.

TOXICOLOGICAL CONCERN:

USE:

R&D

Pesticide

PRODUCTION:

HIGH

SPECIES:

RAT

LOW

MED

TOXICOLOGICAL CONCERN:

USE:

R&D

Pesticide

PRODUCTION:

HIGH

PRODUCTION:

LOW

PRODUCTION:

MED

PRODUCTION:

HIGH

PRODUCTION:

LOW

PRODUCTION:

MED

PRODUCTION:

HIGH

PRODUCTION:

LOW

PRODUCTION:

MED

UNSPECIFIED Substances - 0191 - 11625, 0381 - 1193, 0591 - 12325, 0791 - 12845, 0991 - 13155
 Results received in test numbers 1191-12325 at Chiswick Laboratory levels of 5, 1.5, 3.0 or 4.00/300 (readable 400)
 to unchanged chloroform extractables between 5 and 2.5 millimolar concentration prior to death. Salivation
 to chloroform chloroform extractables between 5 and 2.5 millimolar concentration prior to death. The number 15
 chloroform extractables were also noted for a few of them. The number 15

30 ppm.